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10/647,796	08/26/2003	Zeev Glozman	P-6165-US	2006

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EXAMINER	
DAY, HERNG DER	

ART UNIT	PAPER NUMBER
2128	

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,796	GLOZMAN ET AL.	
	Examiner	Art Unit	
	Herng-der Day	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-45 have been examined and rejected.

Drawings

2. The drawings are objected to for the following reasons. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include **all** of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the Examiner, the Applicants will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2-1. As shown in step 1100 of Fig. 10, it appears that "Acquisition of of a set of images" should be "Acquisition of a set of images"

2-2. Steps 1120 and 1140 of Fig. 10 are not legible.

2-3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

(a) Manual marking of common points 1130, as described in line 16 of page 15.

Specification

3. The disclosure is objected to because of the following informalities. Appropriate correction is required.

3-1. As described in lines 10-11 of page 4, "the segmenting step is performed manually by a medical expert_(In another preferred embodiment of the present invention". (Emphasis added.)

3-2. As described in line 30 of page 4, "(he uses this word too often)". (Emphasis added.)

3-3. A period is missed at the end of paragraph [00012].

3-4. It appears that "Fig. 8A", as described in line 24 of page 7, should be "Fig. 8B".

3-5. It appears that "to select a procedure form a plurality of medical procedures supported by the software", as described in lines 28-29 of page 15, should be "to select a procedure from a plurality of medical procedures supported by the software".

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for steps recited in claim 1, does not reasonably provide enablement for the further limitation of the means plus function as recited in claim 24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 24 is a method claim depends on claim 1. However, claim 24 further comprises means plus function that the specification does not disclose how to make and use it within method steps.

6. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for steps recited in claim 1, does not reasonably provide enablement for the further limitation of the means plus function as recited in claim 29. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 29 is an apparatus claim depends on method claim 1. However, claim 29 additionally comprises means plus function that the specification does not disclose how to make and use it within method steps.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9-11, 14-15, 18-19, 20-22, and 23-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8-1. Claim 9 recites the limitation "said calibrating" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

8-2. Claim 10 recites the limitation "said calibrating" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

8-3. Claim 11 recites the limitation "said calibrating" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

8-4. Claim 14 depends on itself.

8-5. Claim 18 depends on itself.

8-6. Claim 20 recites the limitation "additionally comprising a step of producing and storing output images" in lines 1-2 of the claim. However, at step c of claim 1, output images have been produced. It is unclear whether the output images produced at this additional step are different from the output images produced at step c of claim 1.

8-7. Claim 23 recites the limitation "said desired result" in line 11 of the claim. There is insufficient antecedent basis for this limitation in the claim.

8-8. Claims 25-28, 30, 35-36, 39-40, and 43 recite the limitation "The apparatus according to claim 24" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claim.

8-9. Claim 29 recites the limitation "The apparatus according to claim 1" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

8-10. Claim 43 recites the limitation "additionally comprising a means for producing and storing output images" in lines 1-2 of the claim. However, claim 23, at line 6, also comprises means for producing output images. It is unclear whether the output images produced by these two means for producing function are the same.

8-11. Claims not specifically rejected above are rejected as being dependent on a rejected claim.

Recommendations

9. Claim 20 recites the limitations "said artificial elements" in line 5 of the claim. For clarification purposes, the Examiner suggests that "said artificial elements" be replaced with "said calibrated artificial elements".

10. Claim 43 recites the limitations "said artificial elements" in line 5 of the claim. For clarification purposes, the Examiner suggests that "said artificial elements" be replaced with "said calibrated artificial elements".

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Krause et al., U.S. Patent 6,711,432 B1 issued March 23, 2004 and filed October 23, 2000.

12-1. Regarding claim 1, Krause et al. disclose a method for preoperative planning and simulating of orthopedic surgical procedures using medical images, comprising inter alia the steps of the following:

a. obtaining and displaying said medical images (readily available and inexpensive regular X-ray images, column 5, lines 58-61);

b. segmenting anatomical structure into segments in said medical images (Segmentation, column 6, lines 52-57); and

c. planning the result of said orthopedic surgical procedure so output images are produced, wherein the obtained output images comprising features selected from the group of a plurality of calibrated organs; a plurality of organ segments; a plurality of calibrated artificial elements;

and/or at least one superposition of said calibrated artificial elements on said calibrated organs and/or organ segments (Figure 4).

12-2. Regarding claim 2, Krause et al. further disclose comprising dynamic rendering of medical device form pre defined members, the method allowing dynamic rendering of medical devices with a pre defined relationship, wherein two or more members can be integrated to one member in runtime according to a predefined rule (multifunctional markers 110, column 10, line 25-28).

12-3. Regarding claim 3, Krause et al. further disclose wherein said medical images are X-ray images (regular X-ray images, column 5, lines 58-61).

12-4. Regarding claim 4, Krause et al. further disclose wherein said medical images are combination of plurality of imaging techniques (fusing selective volumetric MRI/CAT scan data, column 8, lines 4-14).

12-5. Regarding claim 5, Krause et al. further disclose wherein said medical images comprising a plurality of views of said anatomical structure (a series of two-dimension representations of the patient's bone, column 6, lines 42-51).

12-6. Regarding claim 6, Krause et al. further disclose wherein the obtaining step comprising transforming of said medical images to digital images (until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone, column 7, lines 21-44).

12-7. Regarding claim 7, Krause et al. further disclose wherein said obtaining includes composing of several images of the same anatomical structure into a full-length view of said anatomical structure (use several regular X-ray images of the patient, column 6, lines 42-51).

12-8. Regarding claim 8, Krause et al. further disclose wherein the obtaining step comprising calibrating of images (An additional level of free-form deformation may be added for additional accuracy, column 7, lines 45-51).

12-9. Regarding claim 9, Krause et al. further disclose wherein said calibrating comprising registration of different views (to more closely match the two-dimensional segmented bone images, column 7, lines 9-17).

12-10. Regarding claim 10, Krause et al. further disclose wherein said calibrating comprising dimension and orientation calibration (the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82, column 7, lines 9-17).

12-11. Regarding claim 11, Krause et al. further disclose wherein said calibrating comprising image enhancements comprising brightness and contrast adjustments, and edge detection (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

12-12. Regarding claim 12, Krause et al. further disclose wherein the segmenting step is performed manually by a medical expert, or automatically, in the manner that the anatomical structure segments are segmented according to predefined rules, or semi-automatically, in the manner that the segmenting step is performed automatically with the assistance of a medical expert (Segmentation may be accomplished using a light board and digitizing stylus, column 6, lines 54-57).

12-13. Regarding claim 13, Krause et al. further disclose wherein the planning step comprising simulating different positioning of said anatomical structure segments (determine the appropriate locations, column 10, lines 8-17).

12-14. Regarding claim 14, Krause et al. further disclose wherein said different positioning of said anatomical structure segments relates to reducing of fractures during trauma treatment (apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

12-15. Regarding claim 15, Krause et al. further disclose wherein said different positioning of said anatomical structure segments relates to pre designed osteotomy treatments for deformed anatomical structures (determine the appropriate locations for the double osteotomy or other multiple orthopedic procedures, column 10, lines 8-17).

12-16. Regarding claim 16, Krause et al. further disclose wherein said artificial elements comprising implants, in the manner that superposition of implants and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, line 25-28).

12-17. Regarding claim 17, Krause et al. further disclose wherein said artificial elements comprise fixation elements, in the manner that superposition of members selected from fixators, fixators anchoring devices, and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, line 25-28).

12-18. Regarding claim 18, Krause et al. further disclose comprising a step of choosing a plurality of said fixation elements from a predefined database (the guides and markers 110 have already been modeled by the planning computer, column 10, lines 34-42).

12-19. Regarding claim 19, Krause et al. further disclose comprising rules for correct positioning of said fixation elements so incorrect positioning of said fixation elements is prevented (determine the appropriate locations, column 10, lines 8-17).

12-20. Regarding claim 20, Krause et al. further disclose additionally comprising a step of producing and storing output images and planning reports of a plurality of alternatives of said steps of segmenting and planning, for the purpose that the best alternative for medical treatment is selected from said alternatives (determine the appropriate locations, column 10, lines 8-17); said planning report comprising part definition of said artificial elements selected for the treatment as well as patient information (preliminary surgical plan, column 10, lines 46-62).

12-21. Regarding claim 21, Krause et al. further disclose additionally comprising a step of providing hard copies of said output images and said planning reports of a selected set of said alternatives (The surgical plan may be sent to the surgeon using various media types, column 11, lines 19-27).

12-22. Regarding claim 22, Krause et al. further disclose additionally comprising a step of communicating said output images and said planning reports to a plurality of remote users (to remotely access other experts, column 2, lines 48-58).

12-23. Regarding claim 23, Krause et al. disclose an apparatus for pre planning and simulating of orthopedic surgical procedures using medical images comprising;

a. segmenting means for defining and marking anatomical structure segments in said medical images (Segmentation, column 6, lines 52-57);

b. planning means for planning the result of said orthopedic surgical procedure, comprising means for producing output images; wherein said output images comprising features selected from the group of a plurality of calibrated organs; a plurality of organ segments; a plurality of calibrated artificial elements; and/or at least one superposition of said calibrated artificial elements on said calibrated organs and/or organ segments (Figure 4);

c. a memory for storing said medical images and said desired result (a planning computer … has developed a detailed preliminary surgical plan, column 11, lines 15-19); and,

d. a display for displaying said medical images and said output images (The surgeon can preferably view the 3D computer simulation or other plan of the surgery, column 11, lines 19-27).

12-24. Regarding claim 24, Krause et al. further disclose comprising means for dynamic rendering of medical device form pre defined members, allowing dynamic rendering of medical devices with a pre defined relationship, wherein two or more members can be integrated to one member in runtime according to a predefined rule (multifunctional markers 110, column 10, line 25-28).

12-25. Regarding claim 25, Krause et al. further disclose wherein the medical images are X-ray images (regular X-ray images, column 5, lines 58-61).

12-26. Regarding claim 26, Krause et al. further disclose wherein the medical images are combination of a plurality of imaging techniques (fusing selective volumetric MRI/CAT scan data, column 8, lines 4-14).

12-27. Regarding claim 27, Krause et al. further disclose wherein the medical images comprising a plurality of views of the same anatomical structures (a series of two-dimension representations of the patient's bone, column 6, lines 42-51).

12-28. Regarding claim 28, Krause et al. further disclose additionally comprising means for transforming said medical images to digital images (until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone, column 7, lines 21-44).

12-29. Regarding claim 29, Krause et al. further disclose additionally comprising means for composing of several images of the same anatomical structure into a full-length view of said anatomical structure (use several regular X-ray images of the patient, column 6, lines 42-51).

12-30. Regarding claim 30, Krause et al. further disclose additionally comprising calibration means for images (An additional level of free-form deformation may be added for additional accuracy, column 7, lines 45-51).

12-31. Regarding claim 31, Krause et al. further disclose wherein the calibration means are also utilized for registration of different views (to more closely match the two-dimensional segmented bone images, column 7, lines 9-17).

12-32. Regarding claim 32, Krause et al. further disclose wherein the calibration means are also utilized for dimension and orientation calibration (the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82, column 7, lines 9-17).

12-33. Regarding claim 33, Krause et al. further disclose wherein the calibration means are also utilized for image enhancements comprising brightness and contrast adjustments, and edge detection (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

12-34. Regarding claim 34, Krause et al. further disclose wherein the calibration means are also utilized for correction of image distortions (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

12-35. Regarding claim 35, Krause et al. further disclose wherein the segmenting means are manually operated by a medical expert or wherein the segmenting means are automatically operated according to predefined rules, or wherein the segmenting means are operated semi-

automatically in the manner that the segmenting step is performed automatically with the assistance of a medical expert (Segmentation may be accomplished using a light board and digitizing stylus, column 6, lines 54-57).

12-36. Regarding claim 36, Krause et al. further disclose wherein the planning means are additionally utilized for simulating different positioning of said anatomical structure segments (determine the appropriate locations, column 10, lines 8-17).

12-37. Regarding claim 37, Krause et al. further disclose wherein the planning means are utilized for simulating reduction of fractures during trauma treatment (apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

12-38. Regarding claim 38, Krause et al. further disclose wherein said different positioning of said anatomical structure segments relates to pre designed osteotomy treatments for deformed anatomical structures (determine the appropriate locations for the double osteotomy or other multiple orthopedic procedures, column 10, lines 8-17).

12-39. Regarding claim 39, Krause et al. further disclose wherein the artificial elements comprise implants, in the manner that superposition of implants and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, line 25-28).

12-40. Regarding claim 40, Krause et al. further disclose wherein the artificial elements comprising fixation elements, in the manner that superposition of members selected from fixators, fixators anchoring devices, and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, line 25-28).

12-41. Regarding claim 41, Krause et al. further disclose comprising a predefined database comprising predefined sets of fixation elements (the guides and markers 110 have already been modeled by the planning computer, column 10, lines 34-42).

12-42. Regarding claim 42, Krause et al. further disclose comprising means for correct positioning of said fixation elements so incorrect positioning of said fixation elements is prevented (determine the appropriate locations, column 10, lines 8-17).

12-43. Regarding claim 43, Krause et al. further disclose additionally comprising a means for producing and storing output images and planning reports of plurality of alternatives, for the purpose that the best alternative for medical treatment is selected from said alternatives (determine the appropriate locations, column 10, lines 8-17), said planning reports comprising part definition of said artificial elements selected for the medical treatment and patient information (preliminary surgical plan, column 10, lines 46-62).

12-44. Regarding claim 44, Krause et al. further disclose additionally comprising means for creating hard copies of said output images and said planning reports of a selected set of said alternatives (The surgical plan may be sent to the surgeon using various media types, column 11, lines 19-27).

12-45. Regarding claim 45, Krause et al. further disclose additionally comprising communicating means for communicating said output images and said planning reports to remote users (to remotely access other experts, column 2, lines 48-58).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Reference to DiGioia, III et al., U.S. Patent 6,205,411 B1 issued March 20, 2001, and filed November 12, 1998, is cited as disclosing a computer-assisted surgery planner.

Reference to Krause et al., U.S. Patent 6,701,174 B1 issued March 2, 2004, and filed April 7, 2000, is cited as disclosing a computer-aided orthopedic surgery planner.

Reference to Marquart et al., U.S. Patent Application Publication 2005/0267722 A1 published December 1, 2005, and filed December 6, 2004, is cited as disclosing a computer-assisted external fixation apparatus.

Reference to Hanson et al., "OrthoDock - An Image Driven Orthopaedic Surgical Planning System", Proceedings of Twelfth Annual International Conference of the IEEE Engineering in Medicine and Biology Society, November 1990, pages 1931-1932, is cited as disclosing the OrthoDock system.

Reference to Kazanzides et al., "An Integrated System for Cementless Hip Replacement", IEEE Engineering in Medicine and Biology Magazine, May/June 1995, pages 307-313, is cited as disclosing the ORTHODOC preoperative planning system.

Reference to Shahidi et al., "Clinical Applications of Three-Dimensional Rendering of Medical Data Sets", Proceedings of the IEEE, March 1998, pages 555-568, is cited as disclosing the utilization of volumetric rendering of medical image.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Herng-der Day whose telephone number is (571) 272-3777. The Examiner can normally be reached on 9:00 - 17:30.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: (571) 272-2100.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kamini S. Shah can be reached on (571) 272-2279. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Herng-der Day
September 5, 2006 H.D.

KAMINI SHAH
SUPERVISORY PATENT EXAMINER